REMARKS/ARGUMENTS

I. STATUS OF THE CLAIMS

Upon entry of this amendment, claims 42 and 46-52 are pending in this application and are presented for examination. Claims 1-41, 43-45, and 53-56 have been canceled without prejudice to future prosecution.

Claims 42 and 46 have been amended. Support for the amendments to the claims is provided below.

Thus, no new matter has been introduced. As such, Applicant respectfully requests that the amendments to the claims be entered.

II. PRIORITY

The Examiner alleges that the earliest date to which the present claims are entitled to the benefit of priority is October 23, 2000. Applicant respectfully traverses, but because an earlier priority date is not required to obviate the present rejections, Applicant forgoes detailed argument here but reserves the right to demonstrate entitlement to an earlier priority date should the necessity arise.

III. INFORMATION DISCLOSURE STATEMENT (IDS)

The Examiner alleges that the Supplemental IDS filed on May 16, 2008 fails to comply with the provisions of 37 CFR §§1.97-1.98 and MPEP §609 because date information was not provided with the listed references (*see,* Office Action at page 4). In an earnest effort to expedite prosecution of the present case, Applicant resubmits herewith an updated version of the Supplemental IDS filed on May 16, 2008 in which the publication date of each of the references is provided. As such, Applicant respectfully requests that the Examiner consider the references cited in the Supplemental IDS.

IV. REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claims 42, 45-52, and 54 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly adding new matter, lacking sufficient written description, and lacking enablement. To

the extent the rejection applies to the amended claims, Applicant respectfully traverses the rejection.

A. New Matter Rejection

In making this aspect of the rejection, the Examiner alleges that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the claimed invention at the time the application was filed (*see,* Office Action at pages 5-6). In particular, the Examiner contends that the specification does not provide support for using the differential expression of the specific combination of the five genes recited in claim 42 to diagnose UC or CD (*see,* Office Action at page 6).

In an earnest effort to expedite prosecution and without acquiescing on the merits of the rejection, Applicant has amended claim 42 to clarify that an increase in the expression level of ***any*** of the GRO3, HNL, MMP-12, elafin, and COL6A3 genes in a test colon cell relative to the expression level of the same gene in a normal colon cell is associated with an ***IBD phenotype*** in the test colon cell.

Applicant asserts that the instant specification provides adequate support for the entire scope of the presently claimed subject matter. For example, the specification teaches: "The subject method is based on the findings that certain genes are differentially expressed in intestinal tissue of ***IBD*** patients compared with related normal cells, such as normal colon cells. That change can be used to thereby identify or classify ***IBD cells*** by the upregulation and/or downregulation of expression of particular genes" (*see,* page 5, lines 30-34; emphasis added). Table 1 of the instant specification clearly shows that an increase in the expression level of ***any*** of the five claimed genes in a test colon cell relative to a normal colon cell is associated with an ***IBD phenotype***. In particular, Table 1 shows that GRO3 (page 51), HNL (page 51), and COL6A3 (page 56) are ***each*** overexpressed in UC colon cells relative to normal colon cells. Additionally, Table 1 at page 55 shows that MMP-12 and elafin are ***each*** overexpressed in UC and CD colon cells relative to normal colon cells. As such, Applicant submits that the instant

specification demonstrates that overexpression of ***any*** of these five genes in a test (*e.g.*, UC- or CD-derived) colon cell relative to a normal colon cell is associated with an ***IBD phenotype***.

Because UC and CD are clinical subtypes of IBD, a diagnosis of either UC or CD is also a diagnosis of IBD. This assertion is supported by Robbins *et al.* (Pathologic Basis of Disease, 2nd Ed. (1979)), previously cited by the Examiner, which states that "there are many similarities between ulcerative colitis and Crohn's disease, and indeed there is a growing tendency ***to consider them as a single entity - 'inflammatory bowel diseases (IBD)'***" (*see,* Robbins *et al.* at page 982, right column; emphasis added). As a result, Applicant respectfully points out that the overexpression of ***each*** of the five claimed genes in UC colon cells alone or both UC and CD colon cells is equivalent to the overexpression of ***each*** of the five claimed genes in ***IBD colon cells***. In fact, the instant specification teaches that "[n]ucleic acids of the present invention have been identified as differentially expressed in ***IBD cells, e.g., UC- or CD-derived cell lines*** (relative to the expression levels in normal tissue, e.g., normal colon tissue and/or normal non-colon tissue), such as Table 1" (*see,* page 18, line 36 to page 19, line 2; emphasis added). Accordingly, Applicant submits that the instant specification provides adequate support for the association between the overexpression of ***any*** of the GRO3, HNL, MMP-12, elafin, and COL6A3 genes and an ***IBD phenotype*** in a test colon cell.

For the foregoing reasons, the instant specification provides adequate support for the entire scope of the presently claimed methods. Therefore, Applicant respectfully requests withdrawal of this aspect of the rejection under 35 U.S.C. § 112, first paragraph.

B. Written Description Rejection

In making this aspect of the rejection, the Examiner alleges that the specification fails to comply with the written description requirement (*see,* Office Action at page 7). In particular, the Examiner contends that the specification does not provide support for associating an increase in the expression level of the specific combination of the five claimed genes with a UC phenotype (*see,* Office Action at page 8). The Examiner also contends that the specification does not provide support for associating an increase in the expression level of the specific combination of MMP-12 and elafin with a CD phenotype (*see, id.*). The Examiner further

contends that the specification does not provide support for differentiating between UC and CD phenotypes based on the specific combination of the five claimed genes (*see, id.*). In response, Applicant asserts that the specification clearly demonstrates to one of skill in the art that the present inventor was in full possession of the claimed invention at the time of filing.

As explained above, Applicant has amended claim 42 to clarify that an increase in the expression level of ***any*** of the GRO3, HNL, MMP-12, elafin, and COL6A3 genes in a test colon cell relative to the expression level of the same gene in a normal colon cell is associated with an ***IBD phenotype*** in the test colon cell. Applicant submits that Table 1 of the instant specification clearly shows that an increase in the expression level of ***any*** of the five claimed genes in a test colon cell relative to a normal colon cell is associated with an ***IBD phenotype***. In particular, Table 1 shows that GRO3 (page 51), HNL (page 51), and COL6A3 (page 56) are ***each*** overexpressed in UC colon cells relative to normal colon cells. In addition, Table 1 at page 55 shows that MMP-12 and elafin are ***each*** overexpressed in UC and CD colon cells relative to normal colon cells. Because UC and CD are clinical subtypes of IBD, the overexpression of ***each*** of the five claimed genes in UC colon cells alone or both UC and CD colon cells is equivalent to the overexpression of ***each*** of the five claimed genes in ***IBD colon cells***. Thus, Applicant asserts that the instant specification provides adequate support for the presently claimed methods of associating an increase in the expression level of ***any*** of the five claimed genes in a test colon cell relative to a normal colon cell with an ***IBD phenotype*** in the test colon cell.

In the Office Action, the Examiner alleges that the use of the specific combination of the five claimed genes to distinguish or diagnose UC and/or CD is highly unpredictable (*see,* Office Action at page 9). To support this allegation, the Examiner cites two references, Warner *et al.* (*Inflamm. Bowel Dis.*, 8:140-157 (2002)) and Wu *et al.* (*Inflamm. Bowel Dis.*, 13:807-821 (2007)), which allegedly teach that using gene expression profiling to differentiate between UC and CD is highly unpredictable (*see, id.*). However, Applicant asserts that these references are inapplicable to the subject matter of the present invention because the presently claimed methods are ***not*** directed to distinguishing a UC phenotype from a CD phenotype based on the differential expression of the specific combination of GRO3, HNL, MMP-12, elafin, and COL6A3. Rather,

the presently claimed methods are drawn to determining whether a test colon cell has an ***IBD phenotype*** by associating the overexpression of ***any*** of the GRO3, HNL, MMP-12, elafin, and COL6A3 genes with an ***IBD phenotype*** in the test colon cell.

In view of the foregoing remarks, the disclosure of the instant specification is more than adequate to demonstrate to one of skill in the art that Applicant had possession of the presently claimed methods at the time the application was filed. Accordingly, Applicant respectfully requests withdrawal of this aspect of the rejection under 35 U.S.C. § 112, first paragraph.

C. Enablement Rejection

In making this aspect of the rejection, the Examiner alleges that the specification fails to comply with the enablement requirement (*see,* Office Action at page 9). In particular, the Examiner reiterates the allegations made in the written description section of the Office Action and further contends that due to the unpredictability of using the specific combination of the five claimed genes for diagnosing UC and/or CD, undue experimentation would be required (*see,* Office Action at pages 10-12). In response, Applicant asserts that the instant specification provides sufficient guidance to enable one of skill in the art to practice the full scope of the claims without undue experimentation.

As explained above, Applicant has amended claim 42 to clarify that an increase in the expression level of ***any*** of the GRO3, HNL, MMP-12, elafin, and COL6A3 genes in a test colon cell relative to the expression level of the same gene in a normal colon cell is associated with an ***IBD phenotype*** in the test colon cell. Applicant submits that Table 1 of the instant specification clearly shows that an increase in the expression level of ***any*** of the five claimed genes in a test colon cell relative to a normal colon cell is associated with an ***IBD phenotype***. In particular, Table 1 shows that GRO3 (page 51), HNL (page 51), and COL6A3 (page 56) are ***each*** overexpressed in UC colon cells relative to normal colon cells. In addition, Table 1 at page 55 shows that MMP-12 and elafin are ***each*** overexpressed in UC and CD colon cells relative to normal colon cells. Because UC and CD are clinical subtypes of IBD, the overexpression of ***each*** of the five claimed genes in UC colon cells alone or both UC and CD colon cells is

equivalent to the overexpression of ***each*** of the five claimed genes in ***IBD colon cells***. As such, the instant specification provides sufficient guidance to enable one of skill in the art to associate an increase in the expression level of ***any*** of the five claimed genes in a test colon cell relative to a normal colon cell with an ***IBD phenotype*** in the test colon cell.

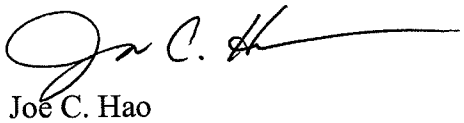
For the foregoing reasons, Applicant asserts that using the guidance provided in the specification, one skilled in the art could practice the full scope of the presently claimed methods without undue experimentation. Therefore, Applicant respectfully requests withdrawal of this aspect of the rejection under 35 U.S.C. § 112, first paragraph.

CONCLUSION

In view of the foregoing, Applicant believes all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,



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